REMARKS

In response to the Office Action dated May 1, 2007, Applicants respectfully submit the present Amendment and Remarks, and reconsideration is respectfully requested.

Amendment to Claims

By this amendment, applicants have amended claims 10 and 20. Claims 13, 14, and 21 are canceled; and claim 22 is newly added.

Applicants respectfully submit that claim 10 has been amended at lines 6-8 to replace the recitation "a solid carrier having a surface having an affinity for cancer cells" with the recitation "magnetic beads having bound to the surfaces thereof an antibody against an antigen on the surface of an epithelial cell and/or epithelial cancer cell." Support for this added recitation can be found at page 11, lines 9-10 of the specification; and in original claim 7. No new matter has been added.

Claim 10 has also been amended at lines 9-10 to add the recitation "a container in which said filtered solution is dispensed and the magnetic beads are added to react each other." Support for this can be found in Figs. 2 and 4; and at page 11, lines 16-23 of the specification. No new matter has been added.

Claim 10 has further been amended at lines 10-12 to replace the recitation "the solid carrier and the filtered solution can be stored" with the recitation "the container being connected to the filter and being provided with an agitating means for agitating at least one of the magnetic beads and the sample." Support for this can be found in original claims 11 and 13. No new matter has been added.

Claim 10 has also been amended line 13 to add the recitation "a dispensing portion for dispensing the filtered solution directly into the container" with the recitation "a recovering magnet which is provided near said container." Support for this can be found in original claim 14. No new matter has been added.

Claim 10 has further been amended lines 14-16 to replace the recitation "a dispensing portion for dispensing the filtered solution directly into the container" with the recitation "a means of magnetic separation to recover cell-beads complex." Support for this can be found in Figs. 2 and 4 of the specification. No new matter has been added.

With regard to claim 20, this claim has been amended to recite "wherein the antibody is a BerEP4 antibody." Support for this can be found at page 11, line 11 of the specification. No new matter has been added.

As for new claim 22, support for this claim can be found in Fig. 4 and in page 13, line 13 to page 14, line 1 of the specification. No new matter has been added.

Applicants respectfully submit that no new matter has been added to amended claims 10 and 20, and new claim 22. Hence, Applicants respectfully request consideration and entry of these claims.

Claims 1-9 have been withdrawn.

Claims 11, 13, 14, and 21 have been cancelled.

Claims 10, 12, 15-20 and 22 are pending in this application.

Withdrawn Rejections

At pages 2-4 of the Office Action, the Examiner has withdrawn the following rejections:

- Rejection of claims 11 and 12 under 35 U.S.C. §112, second paragraph for being indefinite;
- Rejection of claims 10 and 12-15 under 35 U.S.C. §102(e) for being anticipated by Obiso et al.;
- Rejection of claims 10 and 13-15 under 35 U.S.C. §102(b) for being anticipated by Roche et al.;

- Rejection of claims 10 and 13-15 under 35 U.S.C. §102(e) for being anticipated by Nair;
- Rejection of claims 10 and 12-15 under 35 U.S.C. §103(a) for being unpatentable over Roche et al. in view of Trudil et al; and
- Rejection of claims 10 and 12-15 under 35 U.S.C. §103(a) for being unpatentable over Nair in view of Trudil et al.

New rejection under 35 U.S.C.§112, first paragraph

At pages 4-6 of the Office Action, the Examiner rejects claims 10 and 12-21 under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Specifically, the Examiner rejects claim 10 for reciting the recitation "a solid carrier having a surface having an affinity for cancer cells" and the recitation "a dispensing portion for dispensing the filtered solution directly into the container."

Applicants respectfully submit that claim 10 has been amended to remove these recitations. Accordingly, Applicants respectfully request reconsideration and withdrawal of this claim.

As for claim 21, Applicants respectfully submit that this claim has been cancelled.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C.§103

At pages 6-8 of the Office Action, the Examiner rejects claims 10 and 12-21 under 35 U.S.C. §103(a) for being unpatentable over U.S. Patent Publication No. 2003/0059839 to Obiso et al. in view of U.S. Patent No. 6,176,836 B1 to Trudil et al. and WO 97/09600 to O'Neil et al. Applicants respectfully traverse.

The claimed invention

Applicants respectfully submit that the present invention is directed to a cell recovery apparatus recited in amended independent claim 10. The cell recovery apparatus of the present invention comprises (1) a bag for storing a sample comprising a buffer solution and stool at room temperature; (2) a filter by which a stool suspension produced in the bag can be filtered to remove an impurity in the sample and to recover filtered solution; (3) magnetic beads having bound to the surfaces thereof an antibody against an antigen on the surface of an epithelial cell and/or epithelial cancer cell; (4) a container in which said filtered solution is dispensed and the magnetic beads are added to react each other, the container being connected to the filter and being provided with an agitating means for agitating at least one of the magnetic beads and the sample; (5) a recovering magnet which is provided near said container; (6) and a means of magnetic separation to recover cell-beads complex.

In addition, the present invention is also directed to a stool processing total system as recited in newly added 22. The stool processing total system of the present invention comprises means for collecting specimens, means for recovering cell-beads complex, and means for cancer determination. The means for recovering cell-beads complex comprises: (1) a bag for storing a sample comprising a buffer solution and stool at room temperature, (2) a filter by which a stool suspension produced in the bag can be filtered to remove an impurity in the sample and to recover filtered solution, (3) magnetic beads having bound to the surfaces thereof an antibody against an antigen on the surface of an epithelial cell and/or epithelial cancer cell, (4) a container in which said filtered solution is dispensed and the magnetic beads are added to react other, the container being connected to the filter and being provided with an agitating means for agitating at least one of the magnetic

beads and the sample, (5) a recovering magnet which is provided near said container, and (6) a means of magnetic separation to recover cell-beads complex; and wherein the means for cancer determination using the recovered cell-beads complex is selected from the group consisting of cell diagnosis, flow cytometry, DNA diagnosis, and expression analysis utilizing a DNA chip or protein chip.

Applicants respectfully submit that the claimed invention is not taught or suggests by the cited prior art references, either alone or in combination thereof.

In accordance with the apparatus for cell recovery of the present invention, good and living cancer cells can be recovered from stool at room temperature. The apparatus of the present invention can utilize a cell deriving from early colorectal cancer or the stool as a whole as a specimen. Therefore, cancer cells deriving from the ascending colon, which are difficult to detect endoscopically, can be recovered. Furthermore, the apparatus of the present invention has eliminated the centrifugation and cooling operations so that the operation can be simplified and performed in less time. Thus, an automated total system for colorectal cancer examination can be constructed using the cell-beads complex recovered by the present apparatus (see page 7, lines 18-26). In diagnosing colorectal cancer using recovered cells by examining mutations in cancerous cell-derived genes or subtle changes in expression patterns, it becomes possible to evade an influence originated from cells such as other than cancer cells, and to attain a specific effect to provide a diagnosis of high accuracy. If a cell recovery apparatus does not meet any one of the requirements recited in claim 10 is used, cells cannot be recovered in such a high effectiveness which enables to diagnose the colorectal cancer cells from stool. This surprising effect is evidence that the present invention is not obvious from the cited references either alone or in combination thereof.

Obiso et al.

Applicants respectfully submit that the Obiso et al. document is directed to methods for detecting bacterial pathogens using immunoassays. Specifically, the methods of Obiso et al. are used to detect foodborne pathogens in samples, such as fecal specimens, wastewater, drinking water, foods, and beverages. See page 2, paragraph [0016] of Obiso et al. The immunoassays of Obiso et al. comprise linking an antibody to a label, and forming a sandwich immuno-complex comprising two antibodies and a pathogen. See page 3, paragraphs [0039] to [0042]. The label is preferably an electrochemiluminescent compound. See page 6, paragraph [0106], page 9, paragraph [0146].

In the Office Action, the Examiner alleges that the Obiso et al. document teaches the cell recovery apparatus of the present invention because this document allegedly "teaches a cell recovery apparatus containing one or more containers with a solid carrier, such as a magnetic beads and a sterile stomacher-type bag." The Examiner further alleges that a filter is provided and connected in the bag. The Examiner also alleges that Obiso et al. disclose a container for providing agitating means to agitate the sample and the filtering the sample with the filter. The Examiner made these allegations based on paragraphs [0017], [0044], [0138], [0146], [0157], [0103] and [105].

Contrary to the Examiner's allegation, Applicants respectfully submit that the Obiso et al. document does not disclose a cell recovering apparatus containing (1) a bag for storing a sample comprising a buffer solution and a stool at room temperature, and (2) a filter by which a stool suspension produced in the bag can be filtered to remove an impurity in the sample and to recover filtered solution at recited in the independent claims (claims 10 and 22) of the present application.

The only time that Obiso et al. mention a stomacher-type bag is at paragraph [0138]. However, Obiso et al. disclose that this stomacher-type bag is used for enrichment of Listeria species. That is, Obiso et al. disclose the use of a stomacher-type bag to grow Listeria by placing the collected sample with an enrichment broth in the stomacher-type bag, and then incubating it for 35-100 hours at about 30^0C. No filtration step is taken place in the stomacher-type bag.

Hence, there is nothing in the Obiso et al. document that teaches or suggests the use of a stomacher-type bag for recovering epithelial cells, let alone a bag which is connected to a filter to remove impurities.

With regard to paragraphs [0103] and [0105] of the Obiso et al. document cited by the Examiner, Applicants respectfully submit that although these two paragraphs are directed to vortexing the fecal sample and filtering the sample, they are directed to detecting pathogens instead of cancer as recited in the claimed invention. Specifically, paragraph [0104], which is a step taken place between the vortexing step and the filtering step, is a heat activating step to destroy potential for contamination. Further, paragraph [0108] and paragraph [0109], which are the steps following the steps of paragraphs [0103] and [0105], (cited by the Examiner) clearly recite steps involving pathogens instead of cancer as recited in the present claims.

These steps do not take place in a cell recovery apparatus comprising a bag and a filter for removing impurities from stool as recited in the claimed invention as alleged by the Examiner.

Applicants respectfully reiterate that the Obiso et al. document is directed to methods of detecting foodborne pathogens using immunoasays. The examples of the Obiso et al., document are directed to fecal samples collected from patients to detect gastrointestinal diseases. The methods of these examples include diluting fecal samples to form a diluted sample, forming a slurried sample, inactivating the

slurried sample to form an inactivated slurried sample in a heat block at 80^{o} for 15 minutes, adding antibodies, labeling the antibodies, and detecting the emitted luminescence.

There is nothing in the Obiso et al. document that teaches or suggests a cell recovery apparatus for detecting cancer comprising a bag and a filter for removing impurities from stool, let alone an apparatus comprising magnetic beads having bound to the surfaces thereof an antibody against an antigen on the surface of an epithelial cell and/or epithelial cancer cells as claimed in the present invention.

Accordingly, Applicants respectfully submit that Obiso et al. neither teach nor suggest the claimed invention.

Trudil et al. and O'Neil et al.

In addition, the Examiner acknowledges that Obiso et al. do not teach (1) a centrifuge is used in the apparatus, (2) a dispensing portion for dispensing the filtered solution directly into the container and a plurality of filters are between pore size 400 to 1000 μm and the solid carrier is BerEP4 antibody-binding magnetic bead.

To compensate for the deficiencies of Obiso et al., the Examiner cited the Trudil et al. document and the O'Neil et al. document.

Not obvious to combine teachings of Obiso et al. with Trudil et al.

Applicants respectfully submit that there is nothing in the Trudil et al. document or the O'Neil document that teaches or suggests the claimed invention.

The Trudil et al. document is directed to biological sample collection kits. There is nothing in this document that teaches or suggests the use of a bag for recovering epithelial cells, let alone a bag which is connected to a filter to remove impurities.

In addition, there is nothing in the Trudil et al. document that teaches or suggests a cell recovery apparatus for detecting cancer, let alone an apparatus

comprising magnetic beads having bound to the surfaces thereof an antibody against an antigen on the surface of an epithelial cell and/or epithelial cancer cells as claimed in the present invention.

One of ordinary skill in the art would not be motivated to combine (1) the teaching of detecting bacterial pathogens, such as foodborne pathogen as taught in the Obiso et al. document with (2) the teaching of a kit for collecting biological sample as taught in the Trudil document to make a cell recovery apparatus for detecting cancer, let alone an apparatus comprising magnetic beads having bound to the surfaces thereof an antibody against an antigen on the surface of an epithelial cell and/or epithelial cancer cells as claimed in the present invention.

One of ordinary skill in the art would not have been motivated to combine the teachings of Obiso et al. with Trudil et al. to use of a stomacher-type bag for recovering epithelial cells, let alone a bag which is connected to a filter to remove impurities to detect cancer as claimed in the present invention.

Not obvious to combine teachings of Obiso et al. with Trudil et al. and O'Neil et al.

As for the O'Neil et al. document, this document is directed to methods of isolating cells from faecal stool comprising cooling the stool to a temperature below its gel freezing point and removing the cells from the stool while maintaining the stool at a temperature below its gel freezing point such that the stool remain substantially intact.

As discussed above, the apparatus of the present invention provides an efficient way to detect cancer in stool. In accordance with the apparatus for cell recovery of the present invention, good and living cancer cells can be recovered from stool at room temperature. The apparatus of the present invention has eliminated the centrifugation and cooling operations so that the operation can be simplified and performed in less time. Thus, an automated total system for colorectal

cancer examination can be constructed using the cell-beads complex recovered by the present apparatus (see page 7, lines 18-26). In diagnosing colorectal cancer using recovered cells by examining mutations in cancerous cell-derived genes or subtle changes in expression patterns, it becomes possible to evade an influence originated from cells such as other than cancer cells, and to attain a specific effect to provide a diagnosis of high accuracy. If a cell recovery apparatus does not meet any one of the requirements recited in claim 10 is used, cells cannot be recovered in such a high effectiveness which enables to diagnose the colorectal cancer cells from stool.

Applicants respectfully submit that there is nothing in the O'Neil document that teaches or suggests the claimed invention. There is nothing in this document that teaches or suggests the use of a bag for recovering epithelial cells, let alone a bag which is connected to a filter to remove impurities.

One of ordinary skill in the art would not be motivated to combine (1) the teaching of detecting bacterial pathogens, such as foodborne pathogen as taught in the Obiso et al. document with (2) the teaching of a kit for collecting biological sample as taught in the Trudil document together with (3) the teaching of a method of isolating stool by cooling the stool to a temperature below its gel freezing point in the O'Neil document to make a cell recovery apparatus for detecting cancer, let alone an apparatus comprising magnetic beads having bound to the surfaces thereof an antibody against an antigen on the surface of an epithelial cell and/or epithelial cancer cells through the use of a stomacher-type bag for recovering epithelial cells, let alone a bag which is connected to a filter to remove impurities to detect cancer as claimed in the present invention.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, favorable reconsideration and allowance of the application are requested.

To the extent necessary, applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to the deposit account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (Case: 1021.43503X00), and please credit any excess fees to such deposit account.

Respectfully submitted,

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